

**NOVEMBER 2019 PBAC OUTCOMES – OTHER MATTERS**

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>ALECTINIB Capsule 150 mg Alecensa® Roche Products Pty Ltd</p> <p>CRIZOTINIB Capsule 200 mg Capsule 250 mg Xalkori® Pfizer Australia Pty Ltd</p>	<p>Non-small cell lung cancer (NSCLC)</p>	<p>Correspondence from the Medical Oncology Group of Australia (MOGA) requested an increase to the number of repeats for alectinib and crizotinib for the treatment of patients with Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) from 1 to 3.</p>	<p>The PBAC recommended an increase in the number of repeats for the current listings for alectinib and crizotinib, indicated for stage IIIB (locally advanced) or stage IV (metastatic) non-small cell lung cancer, from 1 to 3. The PBAC also advised that this change should also apply to the PBS listing for ceritinib and the recommended listings for lorlatinib and brigatinib.</p>
<p>Authorised Nurse Practitioner prescribing for Hepatitis B (Hep B), Hepatitis C (Hep C) and Human Immunodeficiency Virus (HIV) medicines under the Highly Specialised Drugs (HSD) Program</p>	<p>Agents for the treatment of Hep B, Hep C, and HIV</p>	<p>To endorse the suitability of authorised nurse practitioner prescribing for Hep B, C and HIV medicines under the HSD program</p>	<p>The PBAC endorsed authorised nurse practitioner (NP) prescribing for Hep B, C and HIV medicines under the HSD program.</p> <p>Prescriber eligibility requirements currently in place for the relevant medicines under the <i>National Health (Highly specialised drugs program) Special Arrangement 2010</i> will be extended to NPs, including the accreditation and/or state or territory approval requirements.</p> <p>Enabling NPs to be eligible to prescribe Hep B, C and HIV medicines under the HSD Program is expected to improve access for vulnerable populations including patients in remote and regional areas, those experiencing homelessness, and those in custodial settings.</p>
<p>Post-market Review of Pulmonary Arterial Hypertension (PAH) Medicines AMBRISENTAN BOSENTAN MACITENTAN</p>	<p>Medicines specifically used to treat PAH</p>	<p>Matters relating to the PBAC consideration of the Post-market Review of PAH Medicines report in November 2018</p>	<p>The PBAC considered the outcomes of the stakeholder forum held in June 2019 regarding both the proposed additional change to monotherapy restrictions and the proposed new PBS restrictions for combination use of endothelin receptor antagonist (ERA) and phosphodiesterase-5 (PDE-5) inhibitor medicines for patients with WHO functional class (FC) III/IV PAH symptoms.</p> <p>The PBAC considered the pre-PBAC responses, price proposals from</p>

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<p>EPOPROSTENOL ILOPROST SILDENAFIL (20mg, 90 tablets) TADALAFIL (20mg, 56 tablets) RIOCIGUAT</p> <p>(All forms, strengths and listed brands)</p>			<p>sponsor companies of PAH medicines, correspondence from the Pulmonary Hypertension Society of Australia and New Zealand and estimates of the additional cost to the PBS for combination therapy.</p> <p>The PBAC recommended removing the requirement to demonstrate a response to treatment in the current monotherapy PBS restrictions for all PAH medicines.</p> <p>The PBAC considered and accepted the proposed dual combination therapy PBS restrictions for PAH medicines from the ERA and PDE-5i classes for patients with WHO FC III/IV PAH. PBS listing would be subject to acceptable price reductions from sponsors.</p> <p>The PBAC noted the clinical evidence presented in the PMR Report supported dual combination therapy when a PDE-5i is added to a prostanoid (epoprostenol or iloprost) compared with monotherapy with a prostanoid. The PBAC was of a mind to recommend combination therapy with a prostanoid and sildenafil (or tadalafil at a comparable price) as second line treatment for patients with WHO FC III symptoms and first line treatment for patients with WHO FC IV symptoms. The PBAC requested that the Department present the PBS restrictions and the estimated cost to the PBS for this combination, to the PBAC for consideration.</p>
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